Region 2 Enforcement & Compliance Assurance Division
Air Compliance Branch

CAA Inspection Report

Inspection Date:	12/13/2022
Facility Name:	Curia New York Inc
Facility Address:	33 RIVERSIDE AVENUE, RENSSELAER, NY 12144
ICIS-Air ID #:	NY0000004381400016
Facility Contact:	David Clement, Director, Technical Operations
EPA Led Inspector:	Phillip Ritz, Environmental Scientist
EPA Asst. Inspector:	Joseph Cardile, Environmental Engineer
State Inspector(s):	State inspector name, title, phone number.
Other Inspector(s):	Other inspector name, title, phone number.

Pertinent Regulatory Requirements

Curia (formerly Amri Rensselaer, Inc.) provides global contract research and manufacturing services to the pharmaceutical and biotechnology industries. The Company offers bulk organic and inorganic medicinal chemicals.

Curia Global, Inc., operates as an integrated chemistry outsourcing company. The Company offers, among other things, discovery biology, synthetic and medicinal chemistry, bioanalytical, and small-scale manufacturing services. Curia Global serves pharmaceutical and biotech companies worldwide.

The facility is currently expanding its commercial manufacturing capacity at its facility in Rensselaer, New York. The expansion is for manufacturing and product-handling solutions for complex small molecules. The expansion will include new vessel capacities that more than double the site's batch-size scaling and product output. It will allow for the introduction of new products for high potency API manufacturing.

Entrance Conference

We arrived at the Curia facility in Rensselaer, New York at 9:30 AM on 12/13/22. The weather was clear and sunny. No visible emissions were observed around the perimeter of the facility from the street level. We also observed that the facility consists of many separate buildings. After we showed our credentials to the guard at the guard house entrance to the complex, we were escorted to Curia's administrative office building conference room for an entrance conference. According to a company presentation, Curia's state operating permit limits HAP emissions to 90,000 pounds of VOCs and 47,500 pounds of HAPs per year.

The facility has five large production buildings spread out over 23 acres with approximately 275 employees. The facility operates 24/7 with two 12-hour shifts per day, shutting down for two weeks each year for maintenance. The company is listed as a pharmaceutical company that manufactures over 80 different chemicals and/or drugs. According to facility representatives, most of the facility's products are eventually dried, filtered, and ground to powder format. Significant amounts of organic solvents are used in the manufacturing processes. They limit the pH levels and use scrubbers to control emissions throughout the facility's manufacturing processes. Each production building has at least one scrubber.

The company representatives stated the company was originally known as the AMRI Corporation and was recently re-branded as Curia. Various manufacturing lines at the facility make intermediate and pharmaceutical drugs. The company manufactures drugs used in many clinical studies. Natural gas boilers provide steam and heat. Solvents and raw chemicals used in the manufacturing process arrive in 55-gallon drums or in large plastic totes that each hold 100 gallons.

Company representatives explained that they have plans to expand their manufacturing processes by adding new manufacturing lines in Building 9 and installing two new thermal oxidizers. The company is working with the NYSDEC to modify their current state operating permit to include these new lines/emissions units with a planned construction date in June 2023.

Plant Tour

We started a tour of the facility at 11:00 AM. We first toured the outside area around Building 31. This building houses the raw chemicals and solvents used in various manufacturing processes. The facility stores the hazardous waste generated during manufacturing on the exterior of this building. The hazardous waste is stored in 55-gallon metal drums and 100-gallon plastic totes. We counted over 100 of these metal drums and/or plastic totes stored outside this building. Company representatives explained that they are waiting to be picked up and removed by their waste hauler. Extra waste drums and totes (above what is normally expected) were stored because of a recent snowstorm, and inspectors were told that at least a third of the drums and totes would be removed later in the week.

We next toured Building 38. In this building we observed at least two chemical manufacturing process lines with dedicated internal scrubbers. We then toured Building 2, where we observed at least one manufacturing process line in operation. The air emissions from this line are captured and controlled with a scrubber. It was explained that a new manufacturing process is being planned for startup in this building upon FDA approval. We smelled a slight odor in this building and observed some material dried up on the floor.

Next, we toured Building 33 of the facility. We were told that this building has the largest manufacturing capacity and square footage in the entire facility. They manufacture a variety of different drugs and/or intermediates in this building. We observed at least six different manufacturing or production lines - all these lines can be operating at any given time. This building is also where the facility manufactures amphetamines. Company representatives explained emissions and vapors are low from the various manufacturing processes and vessels in this building. All emissions from these lines are sent to one of two scrubbers in this building.

We next toured Building 19. It was explained that products manufactured in this building are sent over to Building 1 for additional processing. We completed the tour at approximately 12:30 PM and left the facility for lunch.

Final Discussion

The inspectors returned from lunch at 1:30 PM and met with the facility's Environmental, Health and Safety Manager, who showed us a presentation that highlighted the plans for the facility. These plans included installing two (2) new thermal oxidizers, a third boiler, and several bulk tank conversions. The first new thermal oxidizer will be installed in Building 9 and the second oxidizer installed outside Building 19. The third boiler is tentatively planned to be used as a backup boiler. Total modifications/expansions are scheduled for completion in 2027. Company representatives informed us that they have bi-weekly calls with NYSDEC staff to review their planned changes and Title V permit applicability. In the past, the facility had a Title V permit but worked closely with the NYSDEC to implement process changes and product reformulations to limit air emissions to below major source thresholds. The NYSDEC is tracking the facility's future changes and emissions for possible Title V permit requirements.

We next held a detailed discussion regarding the facilities potential to emit pollutants versus their actual pollutant emissions. Company representatives explained that most of the VOCs/HAPs contained in the raw chemicals and solvents used to manufacture their products go out as hazardous waste with very low VOC/HAP air emissions. We spent time going through the facility's spreadsheets and based on a review of these spreadsheets, overall air emissions from the facility appear to be very low on a weekly, monthly, and annual basis.

Closing Conference

We thanked the facility for their assistance during the inspection. We stated that an email may be forthcoming requesting additional documentation, including a description of the planned expansion/modification and the addition of the new thermal oxidizers, raw material in, waste material going out, and potential to emit calculations, etc. We exited the facility at approximately 3pm.

Lead Inspector's Name: Phillip Ritz, Environmental Scientist

X PHILLIP RITZ Digitally signed by PHILLIP RITZ Date: 2023.02.09 11:32:18 -05'00'

Lead Inspector

Assisting Inspector's Name: Joseph Cardile, Environmental Engineer

X JOSEPH CARDILE Digitally signed by JOSEPH CARDILE Date: 2023.02.09 11:42:49 -05'00'

Assisting Inspector

Supervisor's Name: Nancy Rutherford

X Nancy Rutherford Digitally signed by Nancy Rutherford Date: 2023.02.09 12:52:33 -05'00'

Supervisor